

August 6, 1999

QUALITY MANAGEMENT OF DEFIBRILLATORS

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes minimum standards for quality management of defibrillators at Department of Veterans Affairs (VA) medical centers.

2. BACKGROUND

a. Since 1978, VA has required testing of all medical equipment prior to initial use and periodically thereafter. Equipment tests are based on manufacturers' recommendations and the manner in which the equipment is used.

b. In 1989, because of the increasing role of medical equipment in modern medical practice, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) required a significantly more comprehensive management program for medical equipment. Current JCAHO standards have an extensive recurring training requirement for operators of equipment that is critical in the hospital accreditation process.

c. Recent reviews and surveys of VA medical centers suggest that some aspects of defibrillator care and management require improvements to ensure optimal use of these essential and critical devices.

d. Continued attention to the training of clinical personnel is required to ensure that they are proficient in the operation and testing of specific defibrillator models assigned to their work area. It is necessary to ensure that the testing procedures used by clinical personnel be developed jointly with biomedical engineering personnel and clinical staff at the VA medical center.

e. Requirements specified in this directive should be incorporated into the VA medical center's current Equipment Management Program and may be applicable to other similar types of critical equipment.

3. POLICY: VA policy requires that medical equipment be used in a safe and effective manner. The equipment must be operated, tested, and maintained in accordance with good medical and engineering practices and comply with required standards of accrediting agencies such as JCAHO, the National Fire Protection Association (NFPA), the American Heart Association (AHA), etc.

4. ACTION_

a. VA medical centers must review and, if necessary, modify existing defibrillator care and use programs to include requirements contained in this directive.

b. All defibrillators (including loaned and/or rented units) must be tested prior to initial use in a VA facility, and tested periodically as part of scheduled maintenance.

THIS VHA DIRECTIVE EXPIRES AUGUST 31, 2004

VHA DIRECTIVE 99-038

August 6, 1999

c. The frequency of testing is determined locally taking into account the manufacturer's recommendations, NFPA-99 requirements, and the manner in which the defibrillator is used clinically. In no case shall this test be done less than semiannually. Test criteria must ensure that defibrillators perform according to manufacturer specifications and also include an assessment of the internal batteries.

d. Batteries shall be replaced at least every 2 years. **NOTE:** *More frequent replacement may be necessary.*

e. Qualified biomedical engineering staff and/or contractors are to conduct all scheduled maintenance tests and all results shall be documented. **NOTE:** *Existing VA engineering software (version 7.5 or higher) should be used.*

f. In addition to the scheduled maintenance procedures, defibrillators must be checked regularly by clinical users. Each VA medical center must deploy a program that will:

(1) Specify responsibility for performing operational tests, typically assigned to nurses, physician's assistants, or other suitable clinical staff, depending on where the defibrillator is located within the VA medical center. For example, the charge nurse or a clinical nurse specialist could check a defibrillator in a Coronary Care Unit (CCU).

(2) Assign specific training responsibility for operational testing. Such training programs are to be coordinated with Biomedical Engineering for certification of the technical equipment portion. Staff responsible for operational tests shall be trained on how to conduct the tests for the specific defibrillators that they must check. The training program must be consistent with JCAHO standards requiring initial training and annual continuing education as indicated. **NOTE:** *The training must be documented.*

(3) Include operational testing procedures for each model of defibrillator at the medical center. These procedures shall be developed jointly by appropriate clinical and biomedical engineering staff. **NOTE:** *Manufacturers' recommendations must be consulted in developing these procedures.*

(4) Require operational tests to be performed daily in most cases. **NOTE:** *More frequent or less frequent tests may be indicated depending on the manufacturer's recommendations and intended use.* Specific test criteria will vary among specific models but must include the following:

- (a) Output energy;
- (b) Paddle integrity, including cleanliness;
- (c) Physical inspection of the defibrillator and associated cart, if applicable;
- (d) Inventory of associated supplies;
- (e) Functioning of any indicator lights, such as battery charger;

- (f) Proper functioning of the defibrillator, including the chart recorder;
- (g) Internal battery integrity and assessment;
- (h) Integrity of all medical supplies required on crash carts; and
- (i) Documentation of operational tests.

(5) Perform tests on a defined schedule, not necessarily with each shift change in personnel. For example, a defibrillator may require daily exercising (charge and discharge) to be conducted by one shift and no more than visual inspection, including the cart, to be completed on subsequent shifts for the same day. Such testing could be incorporated into ward routine; for example, the defibrillator is checked daily at 9 a.m. (or midnight for that matter). Special attention should be paid to equipment located in remote areas to ensure that testing of this equipment is performed as required.

(6) Provide instructions for performing operational tests to staff who are assigned to perform the tests, and maintain a copy of device specific instructions in each area where a defibrillator is located.

(7) Ensure that staffs responsible for daily checking of defibrillators are trained on testing procedures as required by JCAHO and that this training is documented. **NOTE:** *Training programs are to be coordinated with Biomedical Engineering.*

e. VA medical centers (Intensive Care Unit) or Critical Care Committees have responsibility for the assessment, planning, implementation and evaluation of the effectiveness of resuscitations. Post-resuscitation critiques are used to evaluate the management of cardiopulmonary arrests in medical centers. One aspect of post-resuscitation evaluations needed by both the ICU Committee and the Safety Committee include issues of equipment function. Cardiopulmonary Resuscitation (CPR) related equipment deficiencies shall be brought to the attention of, and tracked by, both committees. Responsibility for corrective action and follow-up will be assigned to the appropriate committee or service.

f. The VA medical centers defibrillator operational testing programs are evaluated annually. Specific criteria shall be developed to measure performance and for outcomes documented.

NOTE: *Technical assistance to comply with this directive can be obtained by contacting the Chief Consultant, Acute Care Strategic Health Group, Patient Care Services at (202)273-8530 or Chief, Biomedical Engineer, Chief Network Office at (202) 273-5881.*

5. REFERENCES

- a. Manufacturers' guidelines.
- b. DM&S Supplement to MP-3.
- c. NFPA-99.

VHA DIRECTIVE 99-038

August 6, 1999

d. JCAHO Standard.

6. FOLLOW-UP RESPONSIBILITY: Chief Officer, Patient Care Services (11) and the Chief Network Officer (10N) are responsible for the contents of this directive.

7. RESCISIONS: None. This VHA Directive expires the last working day of August 31, 2004.

S/ by M. L. Murphy for
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